December 12, 2022

GT Biopharma and Fate Therapeutics Present Preclinical Data Highlighting Novel Dual Antigen Targeting Approach For The Treatment of AML at ASH 2022

Presentation shows the therapeutic potential of combining iPSC-derived CAR NK cells and NK cell engagers to overcome the clinical heterogeneity of AML

BRISBANE, CALIFORNIA, Dec. 12, 2022 (GLOBE NEWSWIRE) -- GT Biopharma, Inc. (NASDAQ: GTBP) today announced the presentation of new preclinical data at the American Society of Hematology's 64th Annual Meeting (ASH 2022). The presentation highlights the potential of a novel dual antigen targeting approach for the treatment of acute myeloid leukemia (AML) by combining GT Biopharma's Tri-specific Killer Engager (TriKE) with the induced pluripotent stem cell (iPSC) product platform of Fate Therapeutics, Inc. (NASDAQ:FATE).

The poster presentation titled, "A Novel Dual-Antigen Targeting Approach Enables Off-the-Shelf CAR NK Cells to Effectively Recognize and Eliminate the Heterogeneous Population Associated with AML," showcases the phenotypic and functional properties of multiplexed-engineered, iPSC-derived NK cells (α3 MICA/B iNK cells) incorporating four functional modalities: a chimeric antigen receptor (CAR) targeting the α3 domain of MICA/B; a high-affinity, non-cleavable CD16 Fc receptor; an IL-15 fusion receptor; and a knock-out of *CD38*. In preclinical models, α3 MICA/B iNK cells demonstrated potent anti-leukemic activity against AML cell lines, and the kinetics of cytotoxicity were enhanced in combination with an anti-CD33 TriKE (GTB-3650).

Jeffrey Miller*, MD, Deputy Director of the University of Minnesota's** Masonic Cancer Center and Consulting Chief Scientific Officer of GT Biopharma noted, "The preclinical data suggest that dual-antigen targeting strategies using iPSC-derived CAR NK cells in combination with antigen-specific TriKE targeting CD33 are a promising approach to address the clinical heterogeneity of AML and enhance outcomes for patients with advanced disease."

Conclusions

- α3 MICA/B iNK cells exhibited antigen-specific activation *in vitro* as measured by interferon-gamma production and CD107a degranulation across a broad range of solid tumor cell lines.
- α3 MICA/B iNK cells demonstrated robust cytotoxicity *in vitro* against an array of AML

cell lines, including those with proteolytic cleavage of the α1 and α2 domains of MICA/B, which is a known mechanism of tumor escape from NK cell cytotoxicity. The kinetics of cytotoxicity were enhanced in combination with GTB-3650, a second-generation anti-CD33 TriKE.

- An analysis of bone marrow aspirates from patients with AML showed high expression of the α3 domain, and low expression of the α1 and α2 domains, of MICA/B, suggesting that the combination of α3 MICA/B iNK cells with GTB-3650 may represent a unique dual-antigen targeting approach to improve anti-leukemic activity in patients with AML.

Poster Presentation

Title: A Novel Dual-Antigen Targeting Approach Enables Off-the-Shelf CAR NK Cells to Effectively Recognize and Eliminate the Heterogenous Population Associated with AML
Abstract Number: 4623
Category: Cellular Immunotherapies: Basic and Translational
Presenter: Jeffrey Miller, MD
Date: December 12, 2022
Location and time: Ernest N. Morial Convention Center, Hall D, New Orleans, LA from 6:00pm – 8:00pm ET

About ASH

The American Society of Hematology (ASH) (www.hematology.org) is the world's largest professional society of hematologists dedicated to furthering the understanding, diagnosis, treatment, and prevention of disorders affecting the blood. For more than 60 years, the Society has led the development of hematology as a discipline by promoting research, patient care, education, training, and advocacy in hematology. ASH's flagship journal, Blood (www.bloodjournal.org), is the most cited peer-reviewed publication in the field, and Blood Advances (www.bloodadvances.org) is the Society's online, peer-reviewed open-access journal.

About Fate Therapeutics

Fate Therapeutics is a clinical-stage biopharmaceutical company dedicated to the development of first-in-class cellular immunotherapies for patients with cancer. The Company has established a leadership position in the clinical development and manufacture of universal, off-the-shelf cell products using its proprietary induced pluripotent stem cell (iPSC) product platform. The Company's immuno-oncology pipeline includes off-the-shelf, iPSC-derived natural killer (NK) cell and T-cell product candidates, which are designed to synergize with well-established cancer therapies, including immune checkpoint inhibitors and monoclonal antibodies, and to target tumor-associated antigens using chimeric antigen receptors (CARs). Fate Therapeutics is headquartered in San Diego, CA. For more information, please visit www.fatetherapeutics.com.

About GT Biopharma, Inc.

GT Biopharma, Inc. is a clinical stage biopharmaceutical company focused on the development and commercialization of immuno-oncology therapeutic products based on our proprietary TriKE® NK cell engager platform. Our TriKE® platform is designed to harness

and enhance the cancer killing abilities of a patient's immune system's natural killer cells. GT Biopharma has an exclusive worldwide license agreement with the University of Minnesota to further develop and commercialize therapies using TriKE® technology. For more information, please visit https://www.gtbiopharma.com/.

GT Biopharma Forward-Looking Statements

Certain statements in this press release may constitute "forward-looking statements" regarding future events and our future results. All statements other than statements of historical facts are statements that could be deemed to be forward-looking statements. These statements are based on current expectations, estimates, forecasts, and projections about the markets in which we operate and the beliefs and assumptions of our management. Words such as "expects," "anticipates," "targets," "goals," "projects", "intends," "plans," "believes," "seeks," "estimates," "endeavors," "strives," "may," or variations of such words, and similar expressions are intended to identify such forward-looking statements. Readers are cautioned that these forward-looking statements are subject to a number of risks, uncertainties and assumptions that are difficult to predict, estimate or verify. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements. Such risks and uncertainties include those factors described in our most recent annual report on Form 10-K, as such may be amended or supplemented by subsequent quarterly reports on Form 10-Q, or other reports filed with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements. The forward-looking statements are made only as of the date hereof, and we undertake no obligation to publicly release the result of any revisions to these forward-looking statements. For more information, please refer to our filings with the Securities and Exchange Commission.

Fate Therapeutics Forward-Looking Statements

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 including statements regarding the therapeutic potential of the Company's iPSC-derived CAR NK cells, including in combination with other therapeutic mechanisms. Any forward-looking statements in this release are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, the risk that the Company's iPSC-derived CAR NK cells may not produce therapeutic benefits or may cause other unanticipated adverse effects. For a discussion of other risks and uncertainties, and other important factors, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, see the risks and uncertainties detailed in the Company's periodic filings with the Securities and Exchange Commission, including but not limited to the Company's most recently filed periodic report, and from time to time in the Company's press releases and other investor communications. Fate Therapeutics is providing the information in this release as of this date and does not undertake any obligation to update any forward-looking statements contained in this release as a result of new information, future events or otherwise.

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* Dr. Miller consults for and holds equity in Fate Therapeutics and GT Biopharma.

** The University of Minnesota has a financial interest in certain product candidates of Fate Therapeutics and in certain product candidates of GT Biopharma, including its GTB 3650 product candidate, under its license agreements with Fate Therapeutics and GT Biopharma, respectively.

Source: GT Biopharma, Inc.